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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,609	12/22/2003	Ronald L. Ream	112703-315	7553

29156 7590 09/15/2005

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,609	REAM ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,10-12,14-18,23 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,10-12,14-18,23 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/07/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination, Information Disclosure Statement, and Amendment filed 07/07/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/07/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18, 23, 25 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the

application was filed, had possession of the claimed invention. Applicant's specification while provides support for absorbing caffeine into systemic system through the oral mucosa, does not appear to provide support for the limitation "absorbing at least a *portion* of the caffeine saliva content through the oral mucosa" of claim 14. It is further appear that applicant's specification does not provide support for the limitation "enterally ingesting caffeine to provide *a first amount* of caffeine in the systemic system" of claim 23; as well as the limitation "second amount of caffeine", and the limitation "the first and second amounts of caffeine providing an effective amount of caffeine in the systemic system" of claim 23. Applicant's specification does not appear to provide support for the limitations a method for reducing the amount of stimulant necessary to deliver an effective amount of stimulant to an individual comprising the step of "adjusting the hydrophilic/lipophilic balance of the stimulant", "blending the medicament with a base/emulsifier system", and "blending occurs before the providing" in claims 27-29.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 10-12 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rejected in the use of the phrase "less than the enteral administration amount". The "enteral administration amount" limits the amount of stimulant to a single, specific dosage of stimulant swallowed to achieve an effect. The specification does not

provide definition or guidance regarding how to select a single, specific dosage of stimulant within the range of "enteral administration amount" that represents the amount to achieve the desired effect.

Claims 27-29 are rejected as being of improper dependent form for failing to further limit the subject matter of claim 7. Claim 7 is a method for delivering stimulant into systemic system through the oral mucosa. The steps in claims 27-29 appear to be steps of method for preparing the chewing gum. Applicant is required to cancel the claims, or amend the claims to place them in proper dependent form, or rewrite them in independent form.

Claim 29 recites the limitation "the blending" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 27 does not recite the limitation "blending".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 8, 10-12, 14-18, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudas et al. WO 98/23165.

Gudas teaches method of controlling release of chewing gum having caffeine as a stimulant effective to increase energy, and reduce drowsiness (see abstract and page 4, lines 13-19). The rate of release is disclosed in page 5, lines 9-18. Gudas is silent as to the teaching of the saliva content of the stimulant (claims 11 and 25), however, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify the chewing gum composition taught by Gudas to obtain a similar saliva content of the stimulant because Gudas discloses the use of caffeine in the same form, *e.g.*, chewing gum; and for the same purpose, namely, to increase energy and reduce drowsiness.

Regarding to claims 14 and 18, the reference differs from the claimed invention by not specifically teaching the chewing time before action is taken. However, it would have been obvious for one of ordinary skill in the art to chew the chewing gum taught by Gudas prior to taking any athlete action to enhance alertness and to increase energy, because Gudas teaches a chewing gum composition containing caffeine to reduce drowsiness and increase energy.

Claims 7, 8, 10-12, 14-18, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being obvious over Song et al. US 6,586,023.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Song teaches a chewing gum composition comprises stimulant, such as caffeine, to be used to enhance performance (column 4, lines 25-67). The caffeine-contain chewing is to be chewed in ten minutes or less before the performance (column 7, lines 67 through column 8, lines 1-4). The daily dosage is two pieces every four hours but not more than four to five times a day (column 8, lines 20-23). Song further teaches the

chewing gum composition allows for delivery of caffeine levels on the order of that found in a cup of coffee (column 4, lines 59-62).

Song does not explicitly teach forcing an effective amount of the stimulant into the systemic system through the oral mucosa. However, it would have been obvious to one of ordinary skill in the art to continue chewing the chewing gum to force an effective amount of caffeine into the systemic system to obtain the desired effect, because Song teaches with an extra five minutes of chewing a caffeine-containing chewing gum a high level of alertness is achieved (column 8, lines 1-4).

It is noted that Song does not teach the chewing gum creates a saliva content of stimulant of approximately 15 to about 440 ppm. However, it is the examiner's position that the chewing gum composition of Song would create a similar saliva content of stimulant because Song teaches the same chewing gum composition, the same chewing time, and the same dosage regiment for the same purpose, namely, to enhance alertness performance.

Response to Arguments

Applicant's arguments filed 07/07/05 have been fully considered but they are not persuasive.

Applicant argues that Song teaches an encapsulated caffeine to deliver the caffeine to the chewer's digestive tract, and to permit larger amounts of caffeine to be incorporated into chewing gum. Thus, Song teaches away from a method of reducing the amount of stimulant necessary to deliver an effective amount of stimulant through

the oral mucosa as recited in claim 7. However, it is noted that the larger amounts of caffeine taught by Song is referred to the amounts of caffeine that can be incorporate into the chewing gum comparing to the conventional un-encapsulate caffeine. This teaching certainly does not suggest increasing the amount of caffeine to achieve an effect. It is further noted that the amount of active/medicament to be incorporated in the chewing gum is the same the amount of active/medicament disclosed in applicant's specification, *e.g.*, 50 micrograms to 500 milligrams (column 7, lines 55-64). Accordingly, Song does not teach away from a method for reducing the amount of stimulant necessary to achieve an effect. In response to applicant's argument that caffeine is delivered to the chewer's digestive tract, it is noted that the encapsulated caffeine is to mask the bitter taste of caffeine, not to prevent the absorption of caffeine through the oral mucosa. Although Song teaches caffeine being ingested into the digestive system, nowhere and nothing in Song prevent the absorption of caffeine into the oral mucosa. Contrary to the applicant's argument, Song teaches the delivery of caffeine systemically in the time that falls within the claimed range, *e.g.* ten minutes or less to achieve the desired effect (column 2, lines 39-40; and column 8, lines 1-4). Furthermore, Song also teaches that the caffeine can be encapsulated or partially encapsulated to provide fast release (column 2, lines 59-62).

Applicant argues that Gudas does not teach or suggest chewing and continuing to chew the chewing gum, thus causing the stimulant to adsorb through the oral cavity as claimed. Gudas relates to masking the unpleasant taste of caffeine by a coating and

not stimulant delivery through the oral mucosa. Therefore, one skilled in the art would recognize that Gudas fails to render obvious the claimed invention. However, it is noted that, first, Gudas teaches the same composition for the same active agent, namely, a chewing gum composition to deliver caffeine (see abstract); second, Gudas teaches a method for controlling the release of caffeine for the same purpose, namely, effectively to increase energy, and reduce drowsiness (see abstract; and page 4, lines 13-19). Thus, it would have been obvious for one skilled in the art to chew and continue chewing to achieve the effect of caffeine, *e.g.*, increasing energy. Accordingly, the 103(a) rejection is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
AU 1615